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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION**

FRESENIUS MEDICAL CARE
HOLDINGS, INC., *et al.*,

Plaintiffs,

v.

BAXTER INTERNATIONAL, INC., *et al.*,

Defendants.

No. C 03-1431 SBA

ORDER

[Docket No 971]

Currently before the Court is Baxter Healthcare Corporation's ("Baxter") Motion for Entry of Permanent Injunction, or Alternatively, for Imposition of an Ongoing Royalty [Docket No. 971]. After reading and considering the arguments presented by the parties, the Court finds this matter appropriate for resolution without a hearing. For the reasons that follow, the Court GRANTS the Motion for Entry of Permanent Injunction.

BACKGROUND

In 2003, plaintiffs Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. ("Fresenius") initiated this lawsuit by filing a complaint for a declaratory judgment of non-infringement and invalidity against Baxter related to U.S. Patent No. 5,247,434 ("434 Patent"), U.S. Patent No. 6,284,131 ("131 Patent"), and U.S. Patent No. 5,744,027 ("027 Patent") (collectively, "patents-in-suit"). Baxter counterclaimed for infringement of each of the patents.

In 2005, the Court granted summary judgment to Baxter that Fresenius infringes Claim 26 of the '434 Patent and Claim 1 of the '131 Patent. After three-plus years of litigation, in June 2006, Fresenius admitted that its 2008K machine infringes the asserted claims of the patents-in-suit. Docket No. 755. The Court then entered a judgment of infringement of those asserted claims. Docket No. 770. The remaining dispute for the jury to resolve was whether Fresenius's 2008K hemodialysis machine infringed upon claims 26 through 31 of the '434 patent, claims 1, 2, 3, 13, 14, 15, and 16 of the '131 patent, claims 7, 11, 14, 15, and 16 of the '027 patent, and claims 5 and 7 of the '476 patent. Fresenius

1 asserted that the claims of these patents were invalid either because they were obvious in light of prior
2 art or because they were anticipated by prior art.

3 The jury returned a unanimous verdict on June 30, 2006, finding in favor of Fresenius on all
4 issues submitted to it. *See* Docket No. 829 . The jury found that all remaining claims were either
5 invalid as obvious or invalid as anticipated, and that the Fresenius 2008K did not infringe on either
6 claim 5 or 7 of the '476 patent. Following the jury's verdict, Baxter moved for judgment as a matter
7 of law and for a new trial, arguing that Fresenius had failed to present evidence to the jury that the
8 patents were invalid, On February 13, 2007, the Court granted Baxter's motion for judgment as a matter
9 of law that the patents were valid and ordered a second trial on damages. Docket No. 874

10 A jury trial for damages owed to Baxter for Fresenius's infringement was held from October 24,
11 2007 to October 29, 2007. The jury returned a verdict that Fresenius owed Baxter \$14,175,000 for
12 Fresenius's past sales of the infringing 2008K machine. Docket No. 962. The jury also found that
13 Fresenius owed Baxter damages for sales of the related disposable products (i.e., dialyzers, concentrates,
14 bloodlines, needles, and solutions) in the amount of \$91,000. On November 7, 2007, the Court entered
15 an order reflecting the verdict. Docket No. 965.

16 Baxter has filed post-trial motions for yet another trial, for entry of a permanent injunction, and
17 for an award of damages including prejudgment interest. Fresenius has filed a motion for review of the
18 clerk's taxation of costs.

19 LEGAL STANDARD

20 "The grant of a patent is the grant of the right to invoke the state's power in order to exclude
21 others from utilizing the patentee's discovery without his consent." *Smith International, Inc. v. Hughes*
22 *Tool Company*, 718 F.2d 1573, 1577 (Fed. Cir. 1983) (citing *Zenith Radio Corp. v. Hazeltine Research*,
23 395 U.S. 100, 135 (1969)). Congress enacted 35 U.S.C. § 283 to protect this right to exclude. *Id.*
24 Pursuant to 35 U.S.C. § 283, injunctions may be granted under the principles of equity to prevent the
25 violation of any rights secured by patent, on such terms as the court deems reasonable." *Id.* "Without
26 the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction
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1 of the value it was intended to have, and would no longer be as great an incentive to engage in the toils
2 of scientific and technological research." *Id.* at 1578.

3 In *eBay Inc. v. MercExchange, L.L.C.*, the Supreme Court directed district courts to apply the
4 well-established four-factor test to requests for injunctive relief in patent cases. *eBay Inc. v.*
5 *MercExchange, L.L.C.*, 126 S.Ct. 1837, 1839 (2006). Under that test, to be awarded injunctive relief,
6 a plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available
7 at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering
8 the balance of hardships between plaintiff and defendant, a remedy in equity is warranted; and (4) that
9 the public interest would not be disserved by a permanent injunction. *Id.*

10 ANALYSIS

11 Baxter moves for entry of permanent injunction, or alternatively, for imposition of an ongoing
12 royalty. [Docket No. 971]. Baxter seeks prospective relief; it does not seek to enjoin users of 2008K
13 machines already in the field, or to enjoin those users from purchasing disposables for those machines.
14 Specifically, Baxter has asked this Court to enter an injunction against sales of 2008K machines
15 beginning 9 months after this Court's Order.

16 In *eBay Inc. v. MercExchange, L.L.C.*, the Supreme Court directed district courts to apply the
17 well-established four-factor test to requests for injunctive relief in patent cases. *eBay Inc.*, 126 S.Ct.
18 at 1839. Under that test, to be awarded injunctive relief, a plaintiff must demonstrate: (1) that it has
19 suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are
20 inadequate to compensate for that injury; (3) that, considering the balance of hardships between plaintiff
21 and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved
22 by a permanent injunction. *Id.*

23 A. Irreparable Harm

24 As the Supreme Court noted in *eBay*, "[f]rom at least the early 19th century, courts have granted
25 injunctive relief upon a finding of infringement in the vast majority of patent cases." *eBay, Inc.* 126
26 S.Ct. at 1841 (Roberts, J., concurring). Courts routinely find irreparable harm, and therefore grant
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1 permanent injunctions where, as here, the infringer and the patentee are direct competitors. *See O2*
2 *Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 2007 WL 869576 at *2 (E.D. Tex. 2007) (granting
3 permanent injunction based on the "high value of intellectual property when it is asserted against a direct
4 competitor in the plaintiff's market"); *Novozymes A/S v. Genencor Int'l, Inc.*, 474 F. Supp. 2d 592, 613
5 (D. Del. 2007) (granting permanent injunction and noting the parties "are head-to-head competitors, and
6 [the patentee] has a right, granted by Congress, not to assist its rival with the use of proprietary
7 technology"). In this case, Baxter and Fresenius are head-to-head competitors in the same market. *See*
8 Oct. 2007 Tr. 168:21-23; June 2006 Tr. 961:4-14; Oct. 2007 Tr. 62:24-63:1. Baxter sells hemodialysis
9 and peritoneal dialysis machines and related disposables, in direct competition with Fresenius. *See* Oct.
10 2007 Tr. 8:23-9:17. The law favors Baxter's right to the full value of its property, particularly the ability
11 to keep it out of its main competitor's hands. *Muniauction, Inc. v. Thomson Corp.*, 502 F.Supp.2d 477,
12 482-84 (W.D. Pa. 2007). Indeed, the principal value of a patent is the right to exclude arch competitors
13 from making, selling and using an infringing product.

14 Additionally, the harm to Baxter's reputation resulting from Fresenius's wrongful appropriation
15 of Baxter's technology forms a basis for injunctive relief. It is well-established that harm to reputation
16 as an innovator is an injury "not compensable by damages." *Muniauction*, 502 F. Supp.2d at 483 ("such
17 a harm is not compensable in damages, and is irreparable, making equitable relief appropriate"); *Black*
18 *& Decker Inc. v. Robert Bosch Tool Corp.*, 2006 WL 3446144 at *4 (N.D. Ill. 2006) (reputation as an
19 innovator harmed by continued selling of infringing product); *Wald v. Mudhopper Oilfield Servs., Inc.*,
20 2006 WL 2128851 at *5-6 (W.D. Okla. 2006) (patentee's "reputation for innovation" was damaged as
21 a result of defendant's infringement).

22 Allowing Fresenius to continue to infringe would irreparably harm Baxter's reputation and
23 goodwill as an innovator, threaten Baxter's extensive investments in research and development, and
24 potentially encourage other companies to infringe Baxter's intellectual property. The evidence at trial
25 showed that Baxter annually invests over half a billion dollars each year on research and development,
26 purchases new technology to expand its reach into new markets, and spends tens of millions of dollars
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1 to license technology from other companies. *See* Oct. 24, 2007 Tr. 169:5-170:9; Oct. 25, 2007 Tr.
2 12:17-19. This investment will be largely for naught, and Baxter's reputation as an innovator and the
3 associated goodwill will be tarnished, if Fresenius, Baxter's arch-rival in the renal field, is allowed to
4 market and sell a product that Baxter, and not Fresenius, invented. Accordingly, this factor favors an
5 injunction.

6 **B. Inadequacy of Monetary Damages**

7 Courts have frequently found that "monetary damages are not an adequate remedy against future
8 infringement because 'the principal value of a patent is its statutory right to exclude.'" *Telequip Corp.*
9 *v. The Change Exchange*, 2006 WL 2385425 at *4-5 (N.D.N.Y. Aug. 15, 2006) (citing *Honeywell Int'l*
10 *Inc. v. Universal Avionics Sys. Corp.*, 397 F. Supp.2d 537, 546 (D. Del. 2005)); *see also* *Boehringer*
11 *Ingelheim Vetmedica v. Schering-Plough*, 106 F. Supp.2d 696, 703 (D.N.J. 2000) ("Where there is no
12 question of future infringement and infringement and validity have already been determined, monetary
13 damages are generally considered inadequate in patent cases.") (emphasis added). As one court recently
14 explained: "[i]f plaintiff cannot prevent its only competitor's continued infringement of its patent, the
15 patent is of little value." *Muniauction*, 502 F. Supp.2d at 482.

16 Here, the loss of goodwill, reputation for innovation, the legal right to exclude, including the
17 right to control the terms of any licensing arrangement, are all forms of irreparable injury that cannot
18 be easily and readily quantified through a simple monetary award. This factor favors an injunction.

19 **C. The Balance of Hardships**

20 The evidence Fresenius offered at trial that it has numerous, easily-implemented alternatives to
21 the patented technology supports a finding that the balance of hardships tips in Baxter's favor.
22 Fresenius's CEO has conceded that "there are a lot of ways to approach data input" and an injunction
23 would not be a "big issue." Mot for New Trial, Ex. 2. Fresenius' lead engineer even listed some of the
24 many inexpensive, non-infringing alternative designs readily available to Fresenius, such as "a mouse,
25 a touch pad, a keyboard, so on and so forth." *See* Oct. 26, 2007 Tr. 472:4-9; *see also* June 2006 Tr.
26 390:3-9. Additionally, Daniel Rubinfeld, Fresenius' damages expert, opined that a "design around" in
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1 the year 2000 would have cost between \$200,000-\$1,000,000 and take about six to nine months to
2 implement. Docket No. 452, Exhibit 1, Rebuttal Expert Report of Daniel L. Rubinfeld, 219.
3 Fresenius's Chairman testified that a touch screen was only \$40 less expensive than using a mouse,
4 keyboard, or scratchpad. Oct. 26, 2007 Tr. 503:24-504:22; *see also* Oct. 25, 2007 Tr. 199:13-17. Based
5 on these admissions, Fresenius cannot be heard to now argue that implementing another input device
6 would cause it undue hardship or disadvantage. *Muniauction*, 502 F. Supp.2d at 484 (W.D. Pa. 2007)
7 (rejecting hardship arguments where "[a]t trial, defendants presented numerous low-cost, easily executed
8 replacements for the [infringing] system").

9 Additionally, in cases where the infringer is capable of selling non-infringing items, the balance
10 of hardships favors the patentee. *MGM Well Servs., Inc. v. Mega Lift Sys. LLC*, 505 F.Supp.2d 359, 379
11 (S.D. Tex. 2007). Fresenius repeatedly argued that the 2008H is an "excellent machine" and performs
12 hemodialysis just as well as the 2008K. *See* Oct. 26, 2007 Tr. 462:3-463:3; June 2006 Tr. 263:12-264:4;
13 310:24-311:21. Having relied upon the 2008H as its "non-infringing alternative" in this litigation,
14 Fresenius cannot now disavow that stance and claim hardship in being made to rely on that machine.

15 Finally, as Baxter rightly points out, any alleged hardship Fresenius claims in having to
16 substitute "a mouse, a touch pad, [or] keyboard" on the 2008K machine will be of its own making. *See*
17 Oct. 26, 2007 Tr. 472:4-9.]. Fresenius stipulated in June of 2006 that it was infringing at least two of
18 the patents, and has been apprised since February 2007 of the Court's determination that it had failed
19 to present sufficient evidence at trial that the patents are invalid. *See* Docket Nos. 370, 874. Although
20 it has had over a year to take commercially reasonable steps to redesign its machine, Fresenius has
21 apparently taken no action to ease any hardship it may suffer as a result of an injunction. *See*
22 *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986) ("[o]ne who elects to
23 build a business on a product found to infringe cannot be heard to complain if an injunction against
24 continuing infringement destroys the business so elected."); *Smith & Nephew v. Synthes*, 466 F. Supp.
25 2d 978, 984 (W.D. Tenn. 2006) (finding hardship for loss of sales and for ceasing operations is not
26 sufficient because they are direct consequences of the illegal patent infringement). Indeed, the Court
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1 finds it somewhat bewildering that, having admitted to infringing the patents nearly two years ago and
2 having known for at least a year that an injunction was all but inevitable, Fresenius has apparently done
3 nothing to implement any alternative to the 2008K. It is Fresenius's burden, and not Baxter's, to taste
4 the bitter fruit of its own inaction. This factor therefore favors an injunction.

5 **C. Whether the Public Interest Would Not Be Disserved By Granting A**
6 **Permanent Injunction**

7 Inherent in the patent right is the right to exclude others from violating the patent during its term.
8 The Federal Circuit has repeatedly emphasized the importance of the right to exclude: "Infringement
9 having been established, it is contrary to the laws of property, of which the patent law partakes, to deny
10 the patentee's right to exclude others from use of his property." *Richardson v. Suzuki Motor Co., Ltd.*
11 868 F.2d 1226, 1246-47 (Fed. Cir. 1989). Moreover, the Federal Circuit has observed that the public
12 interest is clearly served by healthy, fair competition in the dialysis marketplace, which will be achieved
13 by keeping infringing products off the market. *TiVo*, 446 F. Supp.2d at 670.

14 Numerous courts have granted permanent injunctions in cases involving medical devices where,
15 as here, there were alternative products already on the market or available to the infringer. *See*
16 *Innogenetics, N.V. v. Abbott Labs.*, 2007 U.S. Dist. LEXIS 3148, at *1-2 (W.D. Wis. Jan. 12, 2007)
17 (granting permanent injunction, where "other diagnostic techniques exist[ed] and would suffice, even
18 if they are not as effective as the patented technique."); *Smith & Nephew*, 466 F. Supp. 2d 978 (granting
19 permanent injunction enjoining sale of medical related product where, among other things, similar
20 products were available on the market).

21 Fresenius' chief argument against the issuance of an injunction is premised upon concerns for
22 patient safety. Specifically, Fresenius points to: (1) the annual demand for dialysis machines; (2) the
23 lack of proof that other suppliers can meet customer demand; (3) Fresenius' alleged inability to market
24 the 2008H; and (4) the fact that other hemodialysis machines allegedly lack features found in the 2008K.
25 Opp'n at 6-13. All of these concerns, however, are fully addressed by Fresenius's concession that it can
26 implement a redesign of the 2008K in nine months; Fresenius states it "could conceivably have a non-
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1 touchscreen replacement for the 2008K designed, validated, and if necessary submitted for FDA
2 approval, within 9 months.” Opp’n at 10 n.5. Fresenius also concedes that allowing it nine months to
3 redesign “will *guarantee* an uninterrupted supply of machines to the market.” *Id.* (emphasis added).
4 Courts have granted injunctions for medical devices with a transition period in cases where public
5 health concerns exist. *See, e.g., Shiley, Inc. v. Bentley Labs., Inc.*, 601 F. Supp. 964, 971 (C.D. Cal.
6 1985) (granting injunction for medical device with transition period and increased royalty rate).

7 Additionally, as Baxter points out, Fresenius is now singing a far different tune as to the
8 importance of the patented touch screen and the ease of a design-around than it did to the jury during
9 the trial. During the trial, Fresenius argued that the patented touch screen was simply a piece of plastic
10 “slapped [] on a hemodialysis machine,” *see* June 19, 2006 Tr. 148:15-18, and that “[i]f you removed
11 this piece of plastic you could still control the entire machine using these buttons.” Oct. 24, 2007 Tr.
12 148:23-25. However, after employing this argumentative strategy at trial, apparently to some success,
13 it now intimates -- but does not explicitly state, perhaps out of a desire to avoid straightforwardly
14 contradicting the representations it made at trial -- that if Fresenius is forced to produce a machine
15 without the touch screen its business will be destroyed and tens of thousands of hemodialysis patients
16 will suffer as a result. However, this parade of horrors is belied by Fresenius’s own footnoted
17 concession that allowing it nine months to redesign “will guarantee an uninterrupted supply of
18 machines to the market.” Opp’n at 10 n.5. Thus, once Fresenius’s public-interest bluster is put to the
19 side, it is clear that Fresenius agrees -- and is in fact on record as agreeing -- that a design around can
20 be relatively quickly implemented.

21 CONCLUSION

22 Accordingly, Baxter’s Motion for a Permanent Injunction [Docket No. 971] is GRANTED. This
23 matter is referred to a magistrate judge to enforce all provisions as set forth as follows:

24 IT IS HEREBY ORDERED, subject to the conditions relating to the transition period as
25 articulated below, that the plaintiffs Fresenius Medical Care Holdings, Inc. and Fresenius USA, Inc.
26 (collectively “Fresenius”), any of their subsidiaries, and their officers, agents, servant, employees, and
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1 attorneys, and those persons in active concert or participation with any or all of them who receive actual
2 notice of this Permanent Injunction (all of said individuals and entities being referred to herein as the
3 "Fresenius Parties") are hereby permanently enjoined from infringing or inducing the infringement of
4 claims 1-3 and 13-16 of U.S. Patent No. 6,248,131 ("the '131 Patent"); claims 26-31 of U.S. Patent No.
5 5,247,434 ("the '434 Patent"), and claim 11 of U.S. Patent No. 5,744,027 ("the '027 Patent") (all of said
6 patent claims being referred to herein as "Asserted Claims" and all of said patents referred to herein as
7 "Patents-In-Suit"), until the expiration of the Patents-In-Suit, by:

8 (a) making, using, selling, and/or offering to sell in the United States the 2008K
9 hemodialysis machine, any other products that meet all the limitations of the Asserted Claims or any
10 product not more than colorably different from the 2008K hemodialysis machine (collectively referred
11 to herein as "Infringing Products"); and

12 (b) assisting others in making, using, importing, selling and/or offering to sell in the United
13 States any Infringing Products.

14 Nothing in paragraphs (a) and (b) above prevents the Fresenius Parties from continuing to use
15 2008K machines that were already in the field or sold to customers before the date of this Permanent
16 Injunction consistent with the other provisions of this Permanent Injunction. Nothing in this Permanent
17 Injunction prohibits Fresenius from making, using, selling or offering for sale its 2008H hemodialysis
18 machine or any other hemodialysis machine that does not infringe the Patents-In-Suit.

19 IT IS FURTHER ORDERED that the injunction against the activities listed in paragraphs (a)
20 and (b) above shall become effective on January 1, 2009. For purposes of this Permanent Injunction,
21 the period from the date of the jury's verdict until January 1, 2009 shall be known as the Transition
22 Period. IT IS FURTHER ORDERED:

23 (a) Fresenius shall pay to Baxter an ongoing royalty of 10% of the sales price for any
24 Infringing Products that are sold during the Transition Period;

25 (b) Fresenius shall pay a royalty of 7% of the sales price for all Disposable Products linked
26 to sales of Infringing Products from November 7, 2007 until expiration of the Patents-In-Suit. For
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1 purposes of this Permanent Injunction, Disposable Products include dialyzers, concentrates, bloodlines,
2 fistula needles, spare parts and service;

3 (c) Fresenius shall provide payment to Baxter of any royalties due under paragraphs (a) and
4 (b) on a quarterly basis. All royalty payments shall be accompanied by a report indicating the number
5 of units sold and the sales price for all Infringing Products and Disposable Products;


6 (d) Payment not made within the date due under paragraph (c) shall accrue interest at the rate
7 of 10% compounded monthly; and

8 (e) Baxter shall have the right to a full accounting, conducted by an independent third-party,
9 at Baxter's own expense and upon reasonable notice, to assess Fresenius' compliance with any of the
10 terms contained in this Permanent Injunction.

11 Nothing in this Permanent Injunction shall prohibit the Fresenius parties from engaging in the
12 design, development or testing of any product which does not infringe the Patents-In-Suit.

13 IT IS SO ORDERED.

14 Date: 3/21/08

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16 Sandra Brown Armstrong
17 United States District Judge
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